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Attn. Opposition Division

24. 03. 2006

(41)

Our ref. : EP 7892-Be/tk
Your ref. : 93909679.8

Amsterdam, March 23, 2006

Re : Notice of Intervention to the opposition proceedings
against European Patent 656 786 in the name of
Novogen Research Pty Ltd

Dear Sirs,

In response to the Communication dated 9 March 2006, Intervener herewith submits English translations of the Writ and the Decision of the District Court The Hague ("Judgment").

Note that the evidence of the date of the writ can be found in the writ. On page 1, line 1 of the writ the date is announced ("twenty-ninth of November two thousand and five", i.e. 29 November 2005).

The representative,



T. Beetz

Enclosures: English translations

De Vries & Metman, Overschiestraat 180, 1062 XK Amsterdam, The Netherlands,

Tel: +31 (0)20 51 10 930, Fax: +31 (0)20 51 10 931, Internet: www.dvme.nl, E-mail: mail@dvme.nl, Bank ABN Amro No. 47.53.88.496, Giro No. 55.14.688

Op al onze diensten en alle rechtsverhoudingen met derden zijn onze Algemene Voorwaarden van toepassing, waarin een beperking van aansprakelijkheid is opgenomen. Deze Voorwaarden worden op verzoek toegezonden en zijn ook in te zien op www.dvme.nl.
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24. 03. 2006

WRIT OF SUMMONS IN INTERIM INJUNCTION PROCEEDINGS (41)

Today, the twenty-ninth of November two thousand and five, at the request of the company organized under foreign law **NOVOGEN RESEARCH Pty Ltd.**, established and with office at 140 Wicks Road, North Ryde NSW 2113, Australia, electing domicile in this matter in (1075 HH) Amsterdam at De Lairesestraat 111-115, at the office of Brinkhof attorneys, of which office P. Burgers handles this case, and at Noordeinde 33 (2514 GC) in The Hague, at the office of P.J.M. von Schmidt auf Altenstadt, who is appointed the attorney of record and who will act as such in law,

I, Albert Jan Scherpenzeel, bailiff in practice in Amersfoort, with office in Amersfoort at Stadsring 91, also domiciled at this address;

pursuant to a verbal order rendered by the President in interim injunction proceedings (the "President") of the Court of The Hague:

SUMMONSED IN INTERIM INJUNCTION PROCEEDINGS:

1. the private company with limited liability **CARE FOR WOMEN B.V.**, established and with office at Chromiumweg 129 in (3812 NM) Amersfoort, serving my writ at this address, speaking with and leaving a copy of this writ with:

Mrs. C.J.M. van Heest, director

2. the private company with limited liability **CARE FOR WOMEN GROOTHANDEL BV**, established and with office at Chromiumweg 129 in (3812 NM) Amersfoort, serving my writ at this address, speaking with and leaving a copy of this writ with:
etc.

3. the private company with limited liability **CARE FOR WOMEN INTERNATIONAL BV**, established and with office at Chromiumweg 129 in (3812 NM) Amersfoort, serving my writ at this address, speaking with and leaving a copy of this writ with:

etc.

TO:

appear on Monday, the nineteenth of December two thousand and five, at 2 p.m., in person or represented by an attorney of record, at the hearing of the President of the Court of The Hague, doing justice in interim injunction proceedings, which hearing will be held on that date in one of the rooms of the law courts at Prins Clauslaan 60;

WITH THE EXPLICIT NOTIFICATION:

- that upon appearance, a court registry fee of EUR 244.00 will be charged to each of the defendants. Indigent people can be granted a reduction of this fee upon submission to the court registrar of a certificate of indigence, to be issued by the Burgomaster of the municipality;
- that if one of the defendants fails to appear at the hearing and the prescribed terms and formalities have been observed, the Court will declare this/these defendant(s) to be in default and will allow the claims, unless the Court is of the opinion that the claims are unlawful or invalid;
- that if not all of the defendants appear in the proceedings in the prescribed manner and the prescribed terms and formalities have been observed, one judgment will be rendered between the plaintiff and all defendants, which will be deemed to be a judgment in a defended action; and

IN ORDER TO:

hear the following claim submitted on behalf of the petitioner (hereinafter "Novogen") as plaintiff:

INTRODUCTION

The parties

- 1 Novogen is an Australian-American company active in the research, development and marketing of isoflavonoid medicinal products. Care for Women B.V. is involved in providing care to menopausal women, among other things by offering products and services. Care for Women Groothandel B.V. is involved in buying and selling these products, including distributing these products. Care for Women International B.V.'s operations include importing and exporting these products. (**Exhibit 1**: extracts from the Chamber of Commerce.)

The patent

- 2 Novogen is the title holder to European patent EP 0 656 786 (**Exhibit 2**: EP 0 656 786 B1) entitled "use of isoflavone phyto-oestrogen extracts of soy or clover", granted on 15 September 2004 following a grant procedure of more than eleven years. The patent was transferred to Novogen by the first title holder and inventor, Graham Edmund Kelly, residing in Northbridge, Australia. A Dutch translation of the patent will be submitted as **Exhibit 3**.
- 3 During the opposition term, eleven opposing parties lodged opposition against granting the patent. At present, ten opposition proceedings are still pending. However, (virtually) all of the documents have been examined by the European Patent Office ("EPO") or the US Patent and Trademark Office ("USPTO") during the grant procedure. The documents did not stop the EPO and the USPTO from granting the patent. The patent is valid. The invalidity arguments put forward by Care for Women will be discussed in more detail below.
- 4 The patent offers protection for – in short – the use of soy or clover extracts containing phyto-oestrogen isoflavones to produce medicinal products against pre-menstrual syndrome, symptoms associated with menopause or prostrate

cancer. Novogen issued licences to third parties to exploit the invention with regard to soy extracts.

5 **The claims of the patent read as follows:**

1. The use of an isoflavone phyto-oestrogen extract of soy or clover, for the manufacture of a medicament for administration in unit dosage form for the treatment of pre-menstrual syndrome, symptoms associated with menopause, or prostate cancer.
2. A use as claimed in claim 1, wherein the medicament further comprises at least one dietary suitable excipient.
3. A use as claimed in claim 1 or 2, wherein the isoflavone phyto-oestrogen is extracted from soya.
4. A use as claimed in claim 3, wherein the isoflavone phyto-oestrogen is extracted from soya hypocotyls.
5. A use as claimed in claim 1 or 2, wherein the isoflavone phyto-oestrogen is extracted from clover¹.
6. A use as claimed in any one of claims 1 to 4, wherein the isoflavone phyto-oestrogen extract comprises one or more of genistein, daidzein, or glycosides thereof, or metabolites or derivatives thereof.
7. A use as claimed in claim 1 or claim 2, wherein the isoflavone phyto-oestrogen comprises genistein and/or biochanin A : daidzein and/or formononetin, present in a ratio of from about 1:2 to 2:1.
8. A use as claimed in any of claims 1 to 7, wherein the isoflavone phyto-oestrogens are present in an amount from about 20 mg to 200 mg per unit dose, optionally where the amount is 50 mg to 150 mg.
9. A use as claimed in any preceding claim, wherein administration of the medicament is administered at least daily over a period of at least a month.
10. A use as claimed in any preceding claim, wherein the extract includes coumestans, lignans and flavones.
11. A use as claimed in any preceding claim, wherein the unit dosage form is a tablet or capsule.

The products of Care for Women

- 6 The Care for Women defendants produce, use, put on the market, sell, deliver or market the products "Women's Menopause" and "Women's Rode Klaver" or at least they offer these products for other parties, import these products or stock these products. In addition, the Care for Women defendants deliver these products in the various designated countries. Copies of the packaging and consumer information leaflets of these products will be submitted as **Exhibit 4**.

As the different information leaflets clearly show, said products contain isoflavone extracts of red clover and soy ("Women's Menopause") or red clover extracts alone ("Women's Rode Klaver"). The packaging of the two products indicates that these products are intended to be used for symptoms associated with menopause.

- 7 The information leaflet for the "Women's Menopause" product reads as follows under the "Information for the user" heading:

"Women's Menopause is a plant-based supplement for women suffering from menopausal symptoms such as hot flashes and night sweats."

The information leaflet says the following under "composition"

"1 capsule contains red clover extract with 40 mg of isoflavones and soy extract 100 mg with 2 mg of isoflavones, as well as filler (microcrystalline cellulose); the capsule is made of gelatine."

The information leaflet for the "Women's Rode Klaver" product says the following under "Information for the user:

"Women's Rode Klaver is a plant-based supplement for women suffering from menopausal symptoms and night sweats."

and:

"1 capsule contains 40 mg of isoflavones with red clover, filler (microcrystalline cellulose), glidant (silicium dioxide), gelatine."

Infringement per claim

- 8 Both products are medicinal products in the form of a single dose (capsule containing a daily dose). Therefore, in view of what is put forward in par. 7, these products fall within the scope of claim 1.

- 9 According to the information leaflets, both products contain at least one excipient suitable for food (microcrystalline cellulose). This means that the products also fall within the scope of **claim 2**.
- 10 According to the information leaflets, Women's Menopause contains isoflavone extracts of soy and clover and Women's Rode Klaver contains isoflavone extracts of just clover. This means that the products also fall within the scope of **claims 3 and 5**.
- 11 According to the information leaflets, a single dose of Women's Menopause contains a total of 42 mg of isoflavones, and Women's Rode Klaver contains a total of 40 mg of isoflavones. This means that both products have the feature of **claim 8**, namely that each single dose contains approximately 20 mg to 200 mg of isoflavone phyto-oestrogen, optionally an amount between 50 mg and 150 mg. These figures are confirmed – for Women's Menopause – by the results of Novogen's own HPLC analysis of samples of this product (**Exhibit 5**).
- 12 The results of this HPLC analysis also show that Women's Menopause contains genistein and daidzein or glycosides thereof or metabolites or derivatives thereof. This satisfies the feature of **claim 6**. These results also show the feature of **claim 7**. Women's Menopause contains genistein and/or biochanin A: daidzein and/or formononetin, present in a ratio of approximately 1:2 to 2:1.
- 13 Both products are offered in the form of capsules: the feature of **claim 11** is also present.
- 14 In performing the actions mentioned in par. 6 in the Netherlands, Care for Women B.V. uses isoflavone extracts of clover and/or soy to produce a medicinal product, to be administered in a single dose to treat symptoms related to menopause and in this way it infringes claim 1 of the patent in the Netherlands. Through these actions, Care for Women B.V. infringes Novogen's rights on account of claims 2, 3, 5, 8 and 11 (and with Women's Menopause it also infringes these rights from claims 6 and 7) of the patent in the Netherlands.

- 15 By offering, selling and distributing the products mentioned above, Care for Women Groothandel BV and/or Care for Women BV offers, sells and distributes the products directly obtained from the patented work methods of claims 2, 3, 5, 8 and 11 (and also of claims 6 and 7 for Women's Menopause) of the patent. For this reason, they infringe Novogen's rights on account of the patent in the Netherlands.
- 16 By exporting the products mentioned above to other designated countries, Care for Women International B.V. exports the products directly obtained using the patented work methods of claims 2, 3, 5, 8 and 11 (and also of claims 6 and 7 for Women's Menopause), which constitutes imports into or supply to the designated countries, which is an action that constitutes patent infringement under the respective patent legislation in those countries. For this reason, Care for Women International B.V. infringes these claims of the patent in the different designated countries.

Defence of Care for Women to the extent known

- 17 On 1 November 2005, Care for Women B.V.'s attorney answered Novogen's summons dated 17 October 2005 (**Exhibit 6**). The contents of this answer can be summarised as follows:

Validity

- 18 The patent is allegedly invalid with regard to the clover component in light of five specified documents, namely:
- (i) Susan Lark, Chapter 10 of The Menopause Self Help Book, 1990/1992;
 - (ii) Gisela Wilcox et al., Oestrogenic Effects of Plant Foods in Postmenopausal Women, 20 October 1990;

- (iii) N. Beckham, Australian Wellbeing, Herbal Help to Avoid Menopause Symptoms, 1988;
- (iv) N. Beckham, The Family Guide to Natural Therapies, Greenhouse Publications, Female Problems, 1988, page 41; and
- (v) Rami S. Kladas et al., Reproductive and General Metabolic Effects of Phytoestrogens in Mammals, Reproductive Toxicology, Volume 3, Number 2, 1989.

19 The five documents mentioned above are not prejudicial to the validity of the patent. The arguments that Novogen will submit against these documents will be briefly explained below and have been included in detail in the report that will be submitted for the hearing as **Exhibit 7**.

With regard to (i) The Menopause Self Help Book

20 Taking the publication date of this book – "1990/1992" – into account, this publication is not part of the prior art, as the "revised and updated" version – the version used in many opposition proceedings – is dated 1992. Nothing shows that this document was in the public domain before the priority date (19 May 1992); moreover, Novogen denies that this was the case.

With regard to (ii) Wilcox et al.

21 No extracts were used in the study of Wilcox et al. but rather the products themselves (including "soy flour" and "red clover sprouts"). This study did not determine the causal link between the use of isoflavones and the reduction of symptoms associated with menopause.

With regard to (iii) Herbal Help

22 This article does not establish a direct link between the use of isoflavones and menopause, let alone between isoflavone phyto-oestrogen extracts of soy or

clover and menopause. Moreover, the article only refers to the whole clover plant ("sprouts") and not to extracts.

With regard to (iv) The Family Guide

- 23 This publication only refers to soy beans and clover. There is no specific reference to isoflavone phyto-oestrogen extracts of soy or clover.

With regard to (v) Kladas et al.

- 24 This document does not come anywhere near the invention, either, and even leads the skilled person away from the invention: Kladas et al. page 88, conclude: "...while phytoestrogens have a few propitious effects, the majority of the effects are nocuous."

Infringement

- 25 In addition, Care for Women allegedly does not infringe the patent because the red clover component that is used in its products is intended to treat post-menopausal symptoms and not symptoms associated with menopause.
- 26 Claim 1 refers to symptoms associated with menopause (emphasis added). The word "associated" in this phrase expresses that the symptoms, i.e. hot flashes and night sweats, are not limited to the time of menopause (which, strictly speaking, is the moment when the last menstruation stops – menopause is a moment, not a period of time), but which also occur before and after this moment during the period of time referred to as the "change".

Losses

- 27 As a result of the infringing actions described above by the Care for Women defendants, Novogen is suffering losses. It is highly likely that the judge will award a claim for damages in proceedings on the merits. On account of urgency, immediate relief is required with regard to the damages, since the defendants are

all comparatively small businesses and the infringing actions described above constitute the core of their operations and the major source of income. Therefore, there is every chance that they will no longer have any assets to recover the damages from following proceedings on the merits. Thus, Novogen is entitled to and has an (urgent) interest in the advance on the damages claimed under 2 below being awarded.

Relative jurisdiction

- 28 Since this case involves patent infringement, the President of the Court of The Hague has jurisdiction over this case based on Section 80 of the 1995 Dutch Patents Act.

Cross-border jurisdiction

- 29 The President of the Court of The Hague has cross-border jurisdiction with regard to all defendants because they are being summoned in the Member State in which they are domiciled.

CONSEQUENTLY:

That it may please the President of the Court of The Hague, in a judgement:

1. to prohibit each of the defendants from infringing European patent 0 656 786 in the designated countries, at least in the Netherlands, more in particular to apply the work methods of claims 1, 2, 3, 5, 6, 7, 8 and 11 of the patent in the designated countries or at least in the Netherlands and/or by producing, using, putting on the market, selling, supplying and/or otherwise marketing or on behalf of other parties offering, importing or holding stocks of the products directly obtained by using the work methods of claims 1, 2, 3, 5, 6, 7, 8 and 11 of the patent, more in particular the products Women's Menopause and Women's Rode Klaver, in the designated countries or at least in the Netherlands, on pain of a penalty of EUR 50,000 (fifty thousand Euros), payable at once, for every

occurrence or every day – at the plaintiff's discretion – that the defendant(s) in question fail(s) to fully comply with this prohibition;

2. to order the defendants jointly and severally to pay the plaintiff an advance on the damages that the defendants owe as a result of the infringing operations by the defendants in Europe, in the amount of EUR 50,000 (fifty thousand Euros), or at least an amount to be determined by the President in good justice;
3. to order the defendants jointly and severally to pay the costs of the proceedings;
4. to set the term for initiating proceedings on the merits as referred to in Section 260 of the Dutch Code of Civil Procedure at 6 months; and
5. to declare the judgement to be rendered provisionally enforceable.

The costs of this notification for me, the bailiff, amount to EUR 71.93

bailiff

This case is handled by P. Burgers, Brinkhof, De Lairessestraat 111-115, 1075 HH Amsterdam, telephone: +31 20 305 3200, fax: +31 20 305 3239, e-mail: peter.burgers@brinkhof.com.

24.03.2006

judgment

DISTRICT COURT OF THE HAGUE

(41)

Civil Law Sector – Judge in interim proceedings

Case number / cause-list number: 254608 / KG ZA 05-1480

Judgment in interim injunction proceedings of 11 January 2006

In the case of

the legal entity according to foreign law

NOVOGEN RESEARCH PTY LTD.,

having its registered office in North Ryde, Australia,

Plaintiffs in the original complaint

Defendants in the counterclaim

Litigation agent: P.J.M. von Schmidt auf Altenstadt, Master of Law

Counsels: P. Burgers, Master of Law, and M.A.R. Vermunt, Master of Law, in Amsterdam,

versus

1. the private company with limited liability

CARE FOR WOMEN BV,

having its registered office in Amersfoort,

2. the private company with limited liability

CARE FOR WOMEN GROOTHANDEL BV,

having its registered office in Amersfoort,

3. the private company with limited liability

CARE FOR WOMEN INTERNATIONAL BV,

having its registered office in Amersfoort,

Defendants in the original complaint,

Plaintiffs in the counterclaim,

Attorney of record: C.J.J.C. van Nispen,

Counsel: S. Dack, barrister, registered pursuant to Section 16h of the Dutch Counsel Act (*Advocatenwet*).

The parties will further be indicated as Novogen and Care for Women respectively in the single form for the Defendants jointly.

1. Development of the proceedings

Novogen served a writ of 29 November 2005 on Care for Women to appear at the hearing of 19 December 2005 before the Judge for Interim injunctions of this Court. During the hearing the counsels of the Plaintiffs assisted by the patent agents H.W. Prins and M.W.J. B Sjaauw-En-Wa, gave (further) explanations of the claims by means of written summaries of their arguments and exhibits. The counsel of Care for Women, assisted by the patent agent T. Beek, put forward a defence, also by means of a written summary of the argument and exhibits, and concluded that the claims should be rejected. Care for Women filed a Statement including a counterclaim. Next, the parties requested judgment submitting their court documents including their written summaries of the argument.

2. The facts

2.1. Novogen is the party entitled to the European patent EP 0 656 786 titled *Use of isoflavone phyto-oestrogen extracts of soy or clover*, further to be called 'the patent'. The patent was granted on 15 September 2004 on the application of 19 May 1993 with

19 May 1992 as the priority date. To date, 11 oppositions to the patent have been filed at the European Patent Office ('EPO').

2.2. The Patent Claims read as follows in the original English language:

1. *The use of an isoflavone phyto-oestrogen extract of soy or clover, for the manufacture of a medicament for administration in unit dosage form for the treatment of premenstrual syndrome, symptoms associated with menopause, or prostate cancer.*
2. *A use as claimed in Claim 1, wherein the medicament further comprises at least one dietary suitable excipient.*
3. *A use as claimed in Claim 1 or 2, wherein the isoflavone phyto-oestrogen is extracted from soya.*
4. *A use as claimed in Claim 3, wherein the isoflavone phyto-oestrogen is extracted from soya hypocotyls.*
5. *A use as claimed in Claim 1 or 2, wherein the isoflavone phyto-oestrogen is extracted from clover.*
6. *A use as claimed in any one of the Claims 1 to 4, wherein the isoflavone phyto-oestrogen extract comprises one or more of genistein, daidzein, or glycosides thereof, or metabolites or derivatives thereof.*
7. *A use as claimed in Claim 1 or 2, wherein the isoflavone phyto-oestrogen comprises genistein and/or biochanin A: daidzein and/or formononetin, present in a ratio of between 1:2 to 2:1.*
8. *A use as claimed in any of Claims 1 to 7, wherein the isoflavone phyto-oestrogens are present in an amount of between 20 mg to 200 mg per unit dose, optionally where the amount is 50 mg to 150 mg.*
9. *A use as claimed in any preceding Claim, wherein administration of the medicament is administered at least daily over a period of at least a month.*
10. *A use as claimed in any preceding Claim, wherein the extract includes coumestans, lignans and flavones.*
11. *A use as claimed in any preceding Claim, wherein the unit dosage form is a tablet or capsule.*

2.3. The Claims in the Dutch language read:

1. *Toepassing van een isoflavon-fyto-oestrogeen extract van soja of klaver voor de bereiding van een geneesmiddel voor toediening in de vorm van een enkelvoudige dosering voor het behandelen van premenstrueel syndroom, symptomen die met de menopauze zijn verbonden of prostaatkanker.*
2. *Toepassing volgens conclusie 1, waarbij het geneesmiddel verder ten minste een voor voedingsmiddelen geschikte excipient bevat.*
3. *Toepassing volgens conclusie 1 of 2 waarbij het isoflavon-fyto-oestrogeen wordt geëxtraheerd uit soja.*
4. *Toepassing volgens conclusie 3, waarbij het isoflavon-fyto-oestrogeen wordt geëxtraheerd uit sojahypocotylen.*
5. *Toepassing volgens conclusie 1 of 2, waarbij het isoflavon-fyto-oestrogeen wordt geëxtraheerd uit klaver.*
6. *Toepassing volgens één of meer van de conclusies 1 -4, waarbij het isoflavon-fyto-oestrogeenextract één of meer van genisteïne, daïdzeïne omvat of glycosiden daarvan of metaboliëten of derivaten daarvan.*
7. *Toepassing volgens conclusie 1 of conclusie 2, waarbij het isoflavon-fyto-oestrogeen genisteïne en/of biochanine A: daïdzeïne en/of formononetine omvat, aanwezig in een verhouding van ongeveer 1:2 tot 2:1.*
8. *Toepassing volgens één of meer van de conclusies 1 -7 waarbij de isoflavon-fyto-oestrogenen aanwezig zijn in een hoeveelheid van ongeveer 20 mg*

tot 200 mg per enkelvoudige dosering, waarbij de hoeveelheid met name 50 mg tot 150 mg bedraagt.

9. Toepassing volgens één of meer van de voorafgaande conclusies, waarbij het toedienen van het geneesmiddel ten minste dagelijks plaatsvindt gedurende een periode van ten minste een maand.

10. Toepassing volgens één of meer van de voorafgaande conclusies, waarbij het extract coumestanen, lignanen en flavonen bevat.

11. Toepassing volgens één of meer van de voorafgaande conclusies, waarbij de vorm van een enkelvoudige dosering een tablet of capsule is.

2.4. Novogen granted licenses to third parties to exploit the invention with regard to soy extracts.

2.5. Care for Women sells the products *Women's Menopause* and *Women's Rode Klaver*. With regard to the *Women's Menopause* product the following is stated on the instruction leaflet under the heading 'Information for the user':

Women's Menopause is a vegetable-based supplement for women with menopause symptoms such as hot flushes and night sweats.

Under 'composition' in the instruction leaflet it reads:

1 capsule contains red clover extract with 40 mg isoflavones and soy extract 700 mg with 2 mg isoflavones, in addition filler (microcrystalline cellulose) and the capsule is made of gelatine.

With regard to the *Women's Rode Klaver* product, the following is stated under the heading 'Information for the user' of the instruction leaflet:

Women's Rode Klaver is a vegetable-based supplement for women with menopause symptoms and night sweats.

and:

1 capsule contains 40 mg isoflavones with red Clover, filler (microcrystalline cellulose), anti-lumping substance (silicium dioxide), gelatine.

3. The claim, its grounds and defence

3.1. Alleging that Care for Women infringes on their patent rights in the Netherlands and other indicated countries, Novogen demands an injunction on infringement in the indicated countries with regard to the patent with ancillary claims as well as an advance of €50,000 as compensation for the damage they have suffered by the infringing actions.

3.2. In these proceedings Care for Women, when requested, explicitly did not respond to the allegation that selling the *Women's Menopause* and *Women's Rode Klaver* products will infringe the patent. They only put a defence of nullity forward. Their defence, insofar as this is required, will be dealt with below in connection with the adjudication.

3.3. In the counterclaim, alleging that Novogen has already for some time been active in a "publicity campaign" aimed against Care for Women, Care for Women asks that an injunction be imposed on Novogen from notifying third parties that the products of Care for Women are infringing any rights Novogen has. In addition, Care for Women claims that a specification of information about the other party's business relations is given and a letter of rectification is sent. All this is claimed on pain of payment of penalty sums.

3.4. Novogen has put up a reasoned defence against the claims in the counterclaim which, insofar as this is required, will be dealt with below in connection with the adjudication.

4. The adjudication of the dispute

In the claim

Jurisdiction

4.1. The Defendants, Care for Women, are established in the Netherlands, so that according to standard case law the Court has in principle cross-border jurisdiction. Because Novogen has not complied with their obligation to furnish facts about the infringement other than in the Netherlands, for that reason alone – also according to standard case law – any cross-border injunction will be rejected. Because of this, the issue as to whether the lack of cross-border competence does also ensue from art. 22, section 4, of the EEX Regulation, can remain unanswered. The defence with regard to the nullity of the patent only relates to the Dutch part of it, quite apart from the fact that if the nullity of the patent had (also) been invoked according to foreign law, the Judge for Interim injunctions does not have to give a final judgment about the nullity defence but only has to make an appraisal of the way in which the respective foreign Court will judge on this, should the occasion arise.

The validity of the patent

4.2. The defence of Care for Women relates to the validity of the patent. To this end they argue that there is a lack of inventiveness and insufficiency of disclosure. In this connection the following is held.

General, the technical field of the patent

4.3. The invention of the patent aims at treatment of premenstrual syndrome, symptoms associated with the menopause or prostate cancer with phyto-oestrogens. Plants contain a multitude of chemical substances which, after consumption of the plant, can also be absorbed in the (human) body. Included in these substances are the so-called phyto-oestrogens, these are oestrogens, that is to say substances with a hormonal effect, of vegetable origin.

4.4. There are three main categories of phyto-oestrogens. One of them consists of the so-called isoflavones. The patent is aimed at the use of this category in particular. Iso-flavone phyto-oestrogens will after consumption by animals or humans affect biological functioning. This effect is associated with the close structural association between the oestrogens occurring in nature. This way the phyto-oestrogens can copy the effects of endogenous oestrogens (occurring in the body). At cellular level the most important types of phyto-oestrogens work in the same manner, i.e. by binding with oestrogen receptors on the surface of the cell. Such interactions will then lead to a certain biological function of that cell. Phyto-oestrogens are able to combine with the oestrogen receptors due to the fact that the structure of these compounds are very similar to those of endogenous oestrogen. In contrast to the animal oestrogens, phyto-oestrogens only weakly bind to the receptors.

4.5. Endogenous oestrogen and phyto-oestrogen compete with each other for the oestrogen-binding locations on the cells. That is why the phyto-oestrogens have an anti-oestrogen effect. This phenomena is known as competing inhibition,

and this means that the biological effect of an active compound (endogenous oestrogen) is reduced by a competing compound with a target receptor of a similar, but less active, compound.

4.6. At high consumption levels the phyto-oestrogens from food can cause significant physiological effects. This has for instance been observed amongst sheep in Australia grazing on meadows consisting mainly of red clover. This plant can contain phyto-oestrogens up to 5% of the dry weight. The competing, inhibiting effect of the phyto-oestrogens in the food leads to infertility of the sheep.

4.7. The common animal and human food pattern leads to a lower intake of phyto-oestrogens. It is assumed that an average intake level has a favourable effect on health. However, changed eating habits in the Western, developed countries resulted in a negligible intake of phyto-oestrogens. It is assumed that the relative deficiency of phyto-oestrogens in "Western" diets has contributed to the development of "Western diseases" such as breast cancer, cancer of the womb, prostate cancer, pre-menstrual syndrome and the menopause syndrome. All these disorders are more or less associated with the oestrogen metabolism. For instance Japanese and Indian diets contain much more phyto-oestrogens than a Western diet. The phyto-oestrogens in question are isoflavones.

4.8. The favourable effect of phyto-oestrogens has been reported. In research, the diets of women in the change of life have been supplemented by products such as soy, red clover and linseed which have an increased phyto-oestrogen content. This has resulted in an improvement of the menopause complaints.

4.9. One of the problems is that considerable consumption of soy or red clover for instance does not fit in with the Western food pattern. The invention aims to offer a useful food supplement in order to supplement a shortage of isoflavone phyto-oestrogens.

The validity of the patent, inventivity

4.10. When requested, Novogen's counsel stated that the patent claims protection for the invention that the use of extracts, as such well known, for purposes, as such well known, leads to a surprising effect in that sense that the use by consuming extracts, instead of the consumption of the full plant, does not lead to another, or in any event not to a reduced, physiological effect.

4.11. By offering an extract in *unit dosage form* of the plant it is not necessary to consume large quantities of the plant. The Judge understands that thus the problem mentioned under 4.9. is solved.

4.12. It appears from the description of the patent that the concept of 'extract' has to be given a broad description. Both water as well as an organic solvent such as for instance alcohol, could serve as a liquid means of extraction, where all kinds of ratios are allowed (par. 71). The extract will then be concentrated by evaporation.

4.13. All things taken together, this leads the Judge for Interim injunctions provisionally to the conclusion that the patent in essence involves the idea of concentrating the active substances (isoflavone phyto-oestrogen) from the plant, so that the user no longer has to consume large quantities of plant parts, but that he can suffice to the daily intake of for instance a tablet or capsule.

4.14. In connection with the inventiveness the question boils down to the fact as to whether extracting plant parts, for instance red clover or soy, in a water-like or organic liquid, and concentration of this in order to comprise it in a tablet or capsule form (*unit dosage form*), was obvious to the professional at the time of the priority date (19 May 1992).

4.15. Care for Women has argued that this is indeed the case and in doing so relies on a number of documents. Novogen argued that these documents, in any event part of them, have been considered by the EPO in the procedure granting the patent. Because Novogen has not filed the (part of the) documents (relevant to this end) of that procedure, the Judge in interim proceedings cannot take Novogen's allegation as a starting point.

4.16. Care for Women filed (Appendix 11 to Exhibit 4) sections from the handbook *Technologie pflanzlicher Arzneibereitungen*, Stuttgart, 1984. Chapter 7.1 of this book starts with the sentence: *Die Verarbeitung von Pflanzenextracten zu Weichgelatinekapselformen verursacht im allgemeinen keine besonderen Schwierigkeiten*. It reads further that inserting in hard capsules is problematic and it also indicates how plant extracts can easily be converted into tablets.

In addition, pages were filed from the *Lehrbuch der pharmazeutischen Technologie*, Berlin, 1984 (Appendix 13 to Exhibit 4). This includes amongst other things the Chapter *Durch Drogenextraktion gewonnene Arzneiformen* with for instance *Hinweise zur Überführung von Pflanzeninhaltsstoffen in Arzneiformen* and a discourse on the *Prinzipien der Pflanzenextraktion*.

4.17. These texts show that extracting plant parts and inserting the extract into a *unit dosage form* was part of the pharmaceutical technology at the time. Indirectly these sources also show that, by using these techniques, the action of the active ingredient is maintained. The use of these techniques for extracting isoflavone phyto-oestrogens from plant parts of red clover or soy, for instance, is therefore obvious. Because the extracted substances are in the *unit dosage form* present in a concentrated form, it is no surprise that the required oestrogen effect also occurs in this form of administering.

4.18. Other documents filed by Care for Women confirm that these techniques were actually applied before the priority date with regard to the extraction of isoflavone phyto-oestrogens for instance from plant parts of red clover or soy. Including:
J. Sachse, *Quantitative Hochdruckflüssigchromatographie von Isoflavonen in Rotklee (Trifolium pratense L.)*, 1984, (Appendix 1 to Exhibit 4). This for instance gives a description of the extraction of red clover by means of water/alcohol;
D.H. Curnow, *Oestrogenic Activity of Subterranean Clover*, 1953, (Appendix 2 to Exhibit 4), includes a description of the extraction of clover by ethanol;

WO 89/05655 (Appendix 12 to Exhibit 1) relates to a patent for a *Dietary supplement and method for the treatment of menopause and manifestations of ageing*. This discloses the use of oestrogen substances, for instance from soy, for instance in alcohol, which can be offered, for instance, in the form of a capsule;

Grunert et al., *Isoflavone in einigen Weiss- und Rotkleearten und ihre oestrogene Wirksamkeit bei juvenilen Mäusen* (Appendix 8 to Exhibit 11), discloses a research carried out in 1966 where a concentrated extract of clover was made by means of methanol, whereafter this extract was administered to the ordinary food of the test animals (mice) in order to determine any oestrogen effect of the food supplement. This effect was ascertained with regard to red clover, not white clover.

4.19. All this leads to the conclusion that for now it can be assumed that there is a considerable chance that the patent will not survive the oppositions or nullity proceedings due to lack of inventive step.

Injunction against infringement

4.20. Because according to the provisional judgment there is a considerable chance that the patent will be found invalid, a weighing of interests results in the requested injunction on infringement having to be rejected.

4.21. As the party who failed to succeed, Novogen will be ordered to pay the costs of the proceedings in the original complaint.

In the counterclaim

4.22. Care for Women has argued that Novogen has for some time been engaged in a "publicity campaign" aimed against them. Referring to the patent, they demanded that Care for Women's customers discontinue offering and selling the Women's Menopause product. These actions by Novogen are said to be tortious towards Care for Women because Novogen knows or ought to know that there is a good chance that the patent is null and void and will be invalidated in opposition. Care for Women has alleged that they have suffered considerable losses because of this and that they have an interest in rectification of the incorrect statements and ensuring that Novogen is enjoined once again prohibited from making such incorrect statements.

4.23. The starting point is that the holder of an examined and granted European patent does not act unlawfully by invoking this patent in order to maintain his rights. Only a special circumstance would make this otherwise.

4.24. The fact that 19 parties have filed oppositions is on its own not a special circumstance in the sense as set out above. After all, the oppositions do not affect prima facie the validity of the patent. Therefore it is not the case at all that Novogen knows or ought to know that the patent is null and void.

4.25. In sending the demands, Novogen has in actual fact done nothing other than enforce their rights. Their statements were neither incorrect nor unlawful. Therefore there are no grounds for rectification. The injunctions claimed will be rejected.

4.26. The decision of the Court in interim proceedings in the claim the present case is indeed a special circumstance as meant above under 4.23. However, Care for Women has not made it plausible that Novogen will not take due account of this new circumstance.

Such being the case, there are no grounds to prohibit Novogen in advance from making incorrect statements to third parties. The injunction claimed will therefore be rejected.

4.27. As the party who failed to succeed Care for Women will be ordered to pay the costs of the proceedings in the counterclaim.

5. The decision

The Judge for interim injunctions:

In the original complaint:
rejects the claims;

orders Novogen to pay the costs of this lawsuit, until now assessed on the part of Care for Women at €816 for the fee of the litigation agent and €244 for court fees;

declares this judgment on the original complaint, as far as the cost award is concerned, provisionally enforceable.

In the counterclaim:

rejects the claims;

orders Care for Women to pay the costs of this lawsuit, until now assessed on the part of Novogen at €816 for the fee of the litigation agent;

declares this judgment in the counterclaim, as far as the cost award is concerned, provisionally enforceable.

This judgment has been pronounced by Chr. A.J.F.M. Hensen, in the public hearing of 11 January 2006.

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